UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,911	08/13/2001	Mark Zamoyski		7984

7590 06/22/2004

Mark Zamoyski
988 Foothill Drive
San Jose, CA 95123

EXAMINER	
COOK, REBECCA	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/928,911	ZAMOYSKI, MARK	
	Examiner	Art Unit	
	Rebecca Cook	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 9-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject mater which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

The claims are drawn to a method of inhibiting the proliferation of malignant cells in the lungs by inhaling one or more trichothecenes. Claim 10 recites that the trichothecenes is a fragment of sub-unit or trichothecenes or fragment or sub-unit of a sesquiterpene epoxide which still possesses the biological activity of inhibiting protein synthesis.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404):

1) Nature of invention, 2) State of prior art, 3) Level of ordinary skill in the art, 4) Level of predictability in the art, 5) Amount of direction and guidance provided by the inventor, 6) Existence of working examples, 7) Breadth of claims, 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim 9 recites "humans" but the specification states on page 37, second paragraph, that "[t]he compositions of the present invention cannot be administered to infants and young children."

Furthermore, Hintikka reports that the toxic compounds of S. Atra-spores were most likely responsible for the severity of the lung injury (page 69, column 1, paragraph); that inhalation exposure to mycotoxins can either elevate cancer risk or cause kidney damage (abstract); in epidemiological studies, mortality from all cancers and respiratory cancer was higher among workers exposed to airborn mycotoxins (page 67, column 2, paragraph 1).

The specification provides insufficient guidance with regard to the instant compounds elevating cancer risk. Undue experimentation would be required to practice the claimed invention with a reasonable expectation of success.

Claim 10 recites that the trichothecenes is a fragment or sub-unit of trichothecenes or fragment or sub-unit of a sesquiterpene epoxide which still possesses the biological activity of inhibiting protein synthesis. However, the specification does not disclose which fragments or sub-units would have the required biological activity or how to prepare them. It would take undue experimentation to determine which fragment or sub-unit would have the desired activity.

Claims 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9 the use of the plural nouns "humans" and "animals" make it appear that more than one subject is required to be treated.

In claim 9 it is not clear that the composition is administered to the humans or non-humans.

No antecedent basis is seen in claim 9 for the recitation of claim 10 "or fragment or sub-unit or a sesquiterpene epoxide which still possesses the biological activity of inhibiting protein synthesis."

In claim 9 it is not clear if the malignancy which is being treated is lung cancer or another kind of malignancy.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over 4,744,981 (Pavanasasivam).

Pavanasasivam (column 1, lines 65-66 through column 2, lines 1-32) discloses that conjugates of trichothecenes are useful to kill tumor cells. The instant claims differ over Pavanasasivam in reciting that the composition is inhaled. However, Pavanasasivam recites "exposing" the body to the conjugate of a trichothecenes, and this would include inhalation. Furthermore, inhalation therapy is well-known in the pulmonary art.

The claims appear to differ over Pavanasasivam in reciting inhibiting the proliferation of malignant cells in the lungs and the absence of mention of a conjugate. However, the phrase "killing tumor cells" of Pavanasasivam would include the instant

malignant cells in the lungs. Additionally, the instant "comprising" language would include the conjugate of Pavanasasivam.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,342,520. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims read on the method of '520 of inhibiting the proliferation of malignant cells using trichothecenes. The instant claims appear to differ over '520 in reciting inhalation therapy, whereas '520 recites injection into a tumor. However, it would be obvious to one of ordinary skill in the art to use inhalation therapy for delivery to the lung, since that is direct application to a tumor.

Claims 9-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5-6 of copending Application No. 10/295,600. Although the conflicting claims are not identical,

they are not patentably distinct from each other because it would be obvious to one of ordinary skill in the art to use the method of administration '600 for the instant method of treatment. Furthermore, the "comprising" language of the method of administration of '600 could include the instant method of treatment.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (571) 272-0584.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 703-872-9806

Rebecca Cook

Primary Examiner
Art Unit 1614

June 19, 2004